The Establishment of Laboratory Guidelines for Analysis of Bioterrorism Samples

Author: Frank W. Schaefer, III

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On October 25, 2001, Administrator Whitman directed that the Agency's biosafety level 3 microbiology laboratory located in the Andrew W. Briedenbach Environmental Research Center (AWBERC) in Cincinnati, be upgraded in order to increase laboratory capacity in time of national need. A multifaceted effort that resulted required careful coordination involving staff from two ORD Laboratories, the National Exposure Research Laboratory and the National Risk Management Research Laboratory. Other key personnel in this partnership effort included AWBERC facility engineers, safety and health personnel, information technology specialists, and maintenance contractors. Supportive input from other federal organizations, such as the Centers for Disease Control (CDC) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) was also received. This support involved site visits to lab facilities at both CDC and USAMRIID, as well as informational exchanges regarding facility requirements and laboratory operating procedures. This poster describes the critical components of this upgrade and identifies necessary steps taken to establish a laboratory capable of safely analyzing bioterrorism samples for agents such as *Bacillus anthracis*.

In the upgrade effort, we followed the basic guidelines furnished by the Department of Health and Human Services for microbiological and biomedical laboratory safety. These guidelines encompassed laboratory practices and techniques, facility design, safety equipment, the monitoring of analyst health, vermin and insect control, and the control of select agents and specialized reagents. Before work was initiated, the laboratory needed to have protocols which covered all standard operating procedures, quality assurance, chain of custody, and a detailed biosafety plan, with emphasis on the approach used in the event of an accidental spill or exposure. Extensive training in all aspects of the protocols was indicated for each analyst. We carefully examined methods for documenting how and who processed samples since such samples are likely to have forensic significance. The design of the laboratory facility centered around containment and segregation of the sample analyses, so as few people as possible are involved. Persons who are immunocompromised are not permitted access to such a hazardous facility. Key card access through an airlock allowing only authorized personnel into the laboratory ensures this policy. All laboratory benches have impervious surfaces and the walls and floors are sealed, so liquids cannot penetrate them. The laboratory equipment and benches are set up in a fashion to allow routine cleaning and disinfection and there is a sink in each laboratory to facilitate hand washing. Interlocking double door autoclaves, a specialized negative pressure ventilation system, and waste stream treatment are all part of the design. In putting these elements in place, the involvement of experienced ORD microbiologists in every phase of the project was critical to the success of the upgrade effort.

Contact Information: Frank W. Schaefer, III

Microbiologist

National Exposure Research Laboratory

513-569-7222

schaefer.frank@epa.gov